NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. Sections Affected Rulemaking Action

R4-23-110 Amend R4-23-501 Amend R4-23-502 Amend

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 32-1904(A)(1) Implementing statute: A.R.S. § 32-1904(A)(1)

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 8 A.A.R. 797, February 22, 2002

4. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy

4425 W. Olive Ave., Suite 140

Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131

Fax: (623) 934-0583 E-mail: rxcop@qwest.net

5. An explanation of the rule, including the agency's reasons for initiating the rule:

In the five-year rule review approved by G.R.R.C. on September 9, 1997, the Board identified R4-23-502 for amending because it lacks clarity in relation to current statutory definitions. The Board staff decided to amend R4-23-501 by updating the style, format, and language to current standards. The Board staff intends to add the word "label" after the last word "medication" in the definition for "dispensing pharmacist" in R4-23-110 to improve clarity and understandability. A new definition for "dietary supplement" is added to R4-23-110. The heading of R4-23-501 is changed from "Vitamins and Other Substances" to "Dietary Supplements." The rule is amended to reflect the use of the term "dietary supplement" for the word "vitamin." The amended rules will include format, style, and grammar changes necessary to comply with the current Administrative Procedure Act.

The Board believes that approval of these rules will benefit the public health and safety by improving the language that defines the non-drug products that may be marketed to supplement the diet and those persons or firms who may distribute nonprescription veterinary drugs in Arizona.

6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:

Not applicable

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

The rules have no economic impact. The changes involve style, format, punctuation, and grammar necessary to provide a clear, concise, and understandable rule. The changes are nonsubstantive in nature. The term "diet supplement" more clearly describes the classification of products that R4-23-501 is intended to characterize.

The Board, pharmacist, pharmacies, physicians, and the public benefit from a rule that is clear, concise, understandable. The rule establishes the non-drug products that may be marketed to supplement the diet and those persons or firms who may distribute nonprescription veterinary drugs in Arizona.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy

4425 W. Olive Ave., Suite 140

Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131

Fax: (623) 934-0583 E-mail: rxcop@qwest.net

10. The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, July 8, 2002. An oral proceeding is scheduled for:

Date: July 8, 2002 Time: 10:00 a.m.

Location: 4425 W. Olive Ave., Suite 140

Glendale, AZ 85302

A person may request information about the oral proceeding by contacting the person listed above.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section

R4-23-110. Definitions

ARTICLE 5. DRUG CLASSIFICATION

Section

R4-23-501. Vitamins and Other Substances Dietary Supplements

R4-23-502. Veterinary

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to A.A.C. Title 4, Chapter 23:

- "Active ingredient" No change
- "Approved course in pharmacy law" No change
- "Approved Provider" No change
- "Authentication of product history" No change
- "AZPLEX" No change
- "Batch" No change
- "Beyond-use date" No change
- "Biological safety cabinet" No change
- "Certified pharmacy technician" No change
- "Class 100 environment" No change
- "Community pharmacy" No change
- "Component" No change
- "Computer system" No change
- "Computer system audit" No change
- "Container" No change
- "Continuing education" No change
- "Continuing education activity" No change
- "Continuing education unit" or "CEU" No change
- "Contact hour" No change
- "Correctional facility" No change
- "CRT" No change
- "Current good compounding practices" No change
- "Current good manufacturing practice" No change
- "Cytotoxic" No change
- "Day" No change
- "DEA" No change
- "Delinquent license" No change
- "Dietary supplement" means a product used to supplement the human or animal diet that contains one or more ingredients, such as vitamins, minerals, herbs, amino acids, enzymes, fruit or vegetable concentrates or powders, organ concentrates, or beneficial bacteria.
- "Dispensing pharmacist" means a pharmacist who, in the process of dispensing a prescription medication after the complete preparation of the prescription medication and before delivery of the prescription medication to a patient or patient's agent, verifies, checks, and initials the prescription medication label, as required in R4-23-402(A).
- "Drug sample" No change
- "Extreme emergency" No change
- "FDA" No change
- "Immediate notice" No change
- "Inactive ingredient" No change
- "Internal test assessment" No change
- "Limited-service correctional pharmacy" No change
- "Limited-service mail-order pharmacy" No change
- "Limited-service nuclear pharmacy" No change
- "Long-term care consultant pharmacist" No change
- "Lot" No change
- "Lot number" or "control number" No change
- "Materials approval unit" No change
- "Mediated instruction" No change
- "MPJE" No change
- "NABP" No change
- "NABPLEX" No change

- "NAPLEX" No change
- "Other designated personnel" No change
- "Outpatient" No change
- "Outpatient setting" No change
- "Patient profile" No change
- "Pharmaceutical care" No change
- "Pharmacy law continuing education" No change
- "Pharmacy technician" No change
- "Prepackaged drug" No change
- "Provider pharmacist" No change
- "Radiopharmaceutical" No change
- "Radiopharmaceutical quality assurance" No change
- "Radiopharmaceutical services" No change
- "Red C stamp" No change
- "Remote drug storage area" No change
- "Resident" No change
- "Responsible person" No change
- "Score transfer" No change
- "Sight-readable" No change
- "Single-drug audit" No change
- "Single-drug usage report" No change
- "Sterile pharmaceutical product" No change
- "Strength" No change
- "Supervision" No change
- "Supplying" No change
- "Support personnel" No change
- "Transfill" No change
- "Wholesale distribution" No change
- "Wholesale distributor" No change

ARTICLE 5. DRUG CLASSIFICATION

R4-23-501. Vitamins and Other Substances Dietary Supplements

Classification of vitamin dietary supplement products.

- 1. Any vitamin dietary supplement product which that is marketed only for the purpose of supplementing the diet is a non-drug product if the following requirements are met:
 - a. The label supplies adequate information as to the normal intake of each vitamin ingredient contained in the product;
 - b. The label supplies adequate information as to the amount of each vitamin ingredient contained in the product; and
 - c. The product is not held out labeled or marketed for the treatment or prevention of any disease but merely as a food accessory dietary supplement.
- 2. Any vitamin preparation which dietary supplement that is held out labeled or marketed to be a treatment for any deficiency disease, or for the correction of any symptom of disease, or for the prevention, mitigation, or cure of any disease, either by direct statement or by inference, is a drug.

R4-23-502. Veterinary

Veterinary preparations. Veterinary preparations distributed by manufacturers of veterinary supplies which that do not contain the "Rx Only" caution label shall be are classified as patent or proprietary medicines nonprescription drugs and thus may be distributed by any person or firm licensed in this category in addition to being distributed by licensed pharmacies who holds a current Board-issued permit in one of the following designations:

- 1. A nonprescription drug retailer.
- 2. A full-service or nonprescription drug wholesaler; or
- 3. A pharmacy.

NOTICE OF PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES HEALTH CARE INSTITUTIONS: LICENSURE

PREAMBLE

l.	Sections Affected	Rulemaking Action
	Article 8	Amend
	R9-10-801	Amend
	R9-10-802	Amend
	R9-10-803	Renumber
	R9-10-803	New Section
	R9-10-804	Repeal
	R9-10-804	Renumber
	R9-10-804	Amend
	R9-10-805	Repeal
	R9-10-805	New Section
	R9-10-806	Amend
	R9-10-807	Amend
	R9-10-808	Amend
	R9-10-809	Renumber
	R9-10-809	New Section
	R9-10-810	Renumber
	R9-10-810	New Section
	R9-10-811	Renumber
	R9-10-811	New Section
	R9-10-812	Repeal
	R9-10-812	Renumber
	R9-10-812	Amend
	R9-10-813	Renumber
	R9-10-813	Amend
	R9-10-814	Renumber
	R9-10-814	Amend
	R9-10-815	New Section
	R9-10-816	New Section
	R9-10-817	New Section
	R9-10-818	New Section
	R9-10-819	New Section

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 36-132(A) and 36-136(F)

Implementing statutes: A.R.S. §§ 36-405(A) and 36-405(B)(1)

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 7 A.A.R. 2084, May 18, 2001

4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Kathy McCanna, Program Manager

Address: Department of Health Services

Division of Assurance and Licensure, Office of Medical Facilities

1647 E. Morten, Suite 160

Phoenix, AZ 85020

Telephone: (602) 674-9750

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Fax: (602) 395-8913

E-mail: kmccann@hs.state.az.us

or

Name: Kathleen Phillips, Rules Administrator

Address: Arizona Department of Health Services

1740 W. Adams, Suite 102

Phoenix, AZ 85007

Telephone: (602) 542-1264 Fax: (602) 364-1150

E-mail: kphilli@hs.state.az.us

5. An explanation of the rule, including the agency's reasons for initiating the rule:

The rulemaking is specifically authorized under A.R.S. Title 36, Chapter 4, which requires the licensure and regulation of health care institutions, and classes and subclasses of health care institutions, by the Arizona Department of Health Services (Department). 9 A.A.C. 10, Article 8, adopted effective October 30, 1989, contains the minimum standards and requirements for hospices and hospice inpatient facilities. In addition, hospices and hospice inpatient facilities are subject to the general requirements set forth in 9 A.A.C. 10, Article 1. Article 1 addresses general licensure requirements, approval of architectural plans and specifications, initial health care institution license application, health care institution license renewal, time-frames, changes affecting a health care institution license, enforcement actions, provisional health care institution license, and denial, revocation, or suspension of a health care institution license.

The Department has amended 9 A.A.C. 10, Article 8 to update hospice rules and to address issues identified in the 1998 Five-year Review Report approved by the Governor's Regulatory Review Council on October 6, 1998. Specifically, the rules are amended to better protect the public, accurately reflect industry standards and practices, be consistent with state and federal statutes and rules, reflect current Department policy, and conform to current rulemaking format and style requirements.

The rulemaking sets forth definitions and general requirements and prescribes specific standards for:

- General requirements for hospices;
- Licensure and relicensure of hospices;
- Hospice administration and staff;
- Patient admissions and patient plan of care;
- Required hospice services at a patient's residence and while a patient is receiving inpatient services.
- Hospice pharmaceutical services, including the administration of drugs and biologicals;
- Hospice dietary counseling and nutrition services;
- Hospice infection control, environmental safety, and sanitation;
- · Recordkeeping and quality assurance; and
- General requirements for hospice inpatient facilities;
- Licensure and relicensure of hospice inpatient facilities; and
- Hospice inpatient facilities physical plant standards, food service requirements, additional environmental safety and sanitation standards, and disaster preparedness.

The rulemaking also repeals the current R9-10-812, which allows a hospice to request a variance from any rule in 9 A.A.C. 10, Article 8. The rule is repealed because there is no specific statutory authority permitting the Department to approve a rule variance and because every hospice and hospice inpatient facility should comply with the requirements and standards established by the Department to protect the health, safety, and well-being of hospice patients and their families.

6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

Not applicable

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

The rulemaking directly impacts the 40 currently licensed hospices and the 20 currently licensed hospice inpatient facilities operating in Arizona. Of these, 32 are private for-profit businesses and 28 are private non-profit businesses. All can be considered small businesses. The rulemaking also directly impacts the thousands of patients annually served by these hospices and hospice inpatient facilities and their families.

The overall economic impact of the rulemaking on hospices and hospice inpatient facilities is expected to be minimal, with the benefits of the rulemaking outweighing the costs. There will be no new or additional costs to hospice patients or their families as a result of this rulemaking.

The retention of requirements and practices already in rule should have little or no direct impact. The impact of any requirements or practices that have been in place and are now incorporated in rule will be mitigated to the extent that those affected have already incorporated these requirements and practices into their general operations. New requirements and changes in existing requirements designed to improve and better regulate hospices and hospice inpatient facilities and to better protect the public should also have a minimal to moderate economic impact.

Hospices, hospice inpatient facilities, patients, and the general public will benefit from updated rules that are consistent with federal and state statutes and rules, that accurately reflect industry standards and practices, that better protect the public, and that conform to current rulemaking format and style requirements.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Dona Marie Markley, Senior Rules Analyst

Address: Arizona Department of Health Services

Bureau of Emergency Medical Services

1651 E. Morten, Suite 120 Phoenix, AZ 85020

Telephone: (602) 861-0708

Fax: (602) 861-9812

E-mail: dmarkle@hs.state.az.us

or

Name: Kathleen Phillips, Rules Administrator

Address: Arizona Department of Health Services

1740 W. Adams, Suite 102

Phoenix, AZ 85007

Telephone: (602) 542-1264 Fax: (602) 364-1150

E-mail: kphilli@hs.state.az.us

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule; or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

The Department has scheduled the following oral proceedings:

Date: July 3, 2002

Time: 9:00 a.m

Location: Hearing Room

Division of Assurance and Licensure

1647 E. Morten Phoenix, AZ 85020

Nature: Oral Proceeding

Written comment on the proposed rulemaking or the preliminary economic, small business, and consumer impact summary may be submitted to an individual listed in item #4 or #9 until 12:00 p.m., July 3, 2002, the date scheduled for the close of record.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES HEALTH CARE INSTITUTIONS: LICENSURE

ARTICLE 8. HOSPICES; HOSPICE INPATIENT FACILITIES

Section			
R9-10-801.	Definitions		
R9-10-802.	Hospice General requirements Requirements		
R9-10-803.	Application for an Initial Hospice License; Application for Renewal of a Hospice License		
R9-10-804.	Medical advisor		
R9-10-803. <u>R9-10-804.</u> <u>Hospice</u> Administration			
R9-10-805.	Policies and procedures Hospice Staff		
R9-10-806.	Patient Admissions		
R9-10-807.	Patient care plan Plan of Care		
R9-10-808.	Hospice services Services		
R9-10-809.	Hospice Pharmaceutical Services		
R9-10-810.	Hospice Dietary Counseling and Nutrition Services Required For a Patient Receiving Inpatient Services		
R9-10-811.	Hospice Infection Control, Environmental Safety, and Sanitation		
R9-10-812. Variances			
R9-10-809-R9-10-812. Clinical record Hospice Recordkeeping; Patient Clinical Record			
R9-10-810. <u>Hospice</u> Quality <u>assurance</u> <u>Assurance</u>			
R9-10-811-R9-10-814. Inpatient service requirements Hospice Inpatient Facility General Requirements			
R9-10-815.	Application for an Initial Hospice Inpatient Facility License; Application for Renewal of a Hospice Inpatient		
	Facility License		
R9-10-816.	Hospice Inpatient Facility Physical Plant Standards		
R9-10-817.	Hospice Inpatient Facility Food Service		
R9-10-818.	Hospice Inpatient Facility Environmental Safety and Sanitation		
<u>R9-10-819.</u>	Hospice Inpatient Facility Disaster Preparedness		

ARTICLE 8. HOSPICES: HOSPICE INPATIENT FACILITIES

R9-10-801. Definitions

In this Article, unless the context otherwise requires:

- 1. "Bereavement services" means social and emotional support offered to the family for at least 1 year following the death of a patient.
- 1. "Abuse" has the same meaning as in A.R.S. § 46-451.
- 2. "Adverse reaction" means an unexpected outcome that threatens the health or safety of a patient as a result of a hospice service provided to the patient.
- 3. "Admission" or "admitted" means documented acceptance by a hospice of an individual as a patient.
- 4. "Assessment" means an analysis of a patient's hospice service needs.

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- "Attending physician" means an individual licensed under A.R.S. Title 32, Chapter 13 or 17 and designated by a patient or a patient representative to participate in the hospice care the patient receives.
- "Biohazardous medical waste" has the same meaning as in R18-13-1401.
- "Biologicals" has the same meaning as in R18-13-1401.
- "Clinical record" has the same meaning as "medical records."
- 'Communicable disease" has the same meaning as in R-9-6-101.
- 10. "Conspicuously post" means to make visible to patients, patients' families, staff, and hospice visitors by displaying on an object, such as a wall or bulletin board.
- 11. "Continuing education" means instruction that satisfies a requirement for renewing an individual's certification or licensure.
- 12. "Counseling" means advice or guidance provided to a hospice patient by a counselor.
- 13. "Counselor" means a qualified individual who offers advice or guidance to a patient or a patient's family.
- 14. "Department" means the Arizona Department of Health Services.
- 15. "Direction" has the same meaning as in A.R.S. § 36-401.
- 16. "Disaster" means an unexpected occurrence that adversely affects the hospice's ability to provide hospice services.
- 17. "Discarded drug" has the same meaning as in R18-13-1401.

 18. "Document" means to create, sign, and date information in written, photographic, electronic, or other permanent form.
- 19. "Documentation" or "documented" means signed and dated information in written, photographic, electronic, or other permanent form.
- 20. "Drug" has the same meaning as in A.R.S. § 32-1901.
- 21. "Electronic" has the same meaning as in A.R.S. § 44-7002.
- 22. "Evacuation drill" means a response to a planned, simulated event.
- 23. "Exploitation" has the same meaning as in A.R.S. § 46-451.
- 2.24. "Family" means a hospice patient's immediate family consisting of a spouse, sibling, child, parent, grandparent, and/or those individuals or an individual designated as caregivers by the patient.
- 3. "Home health aide services" means the performance of simple procedures as an extension of therapy services, personal care, ambulation and exercise, and household services essential to health care at home.
- 4. "Hospice care team" means a physician, a registered nurse, a counselor, and volunteers.
- 5. "Hospice respite services" means care provided to the patient when necessary to relieve the family caring for the patient. The care may be provided in the patient's residence or an inpatient facility.
- 6. "Hospice service plan" means a detailed plan which identifies the services offered by the hospice and the staff who will provide the services.
- 7. "Inpatient services" means hospice services provided to a patient in a hospital, nursing care institution or other facility which meets the requirements of this Article.
- 25. "Garbage" has the same meaning as in R18-13-302.
- 26. "Governing authority" has the same meaning as in A.R.S. § 36-401.
- 27. "Health care institution" has the same meaning as in A.R.S. § 36-401.
 28. "Highly susceptible populations" has the same meaning as in § 1-201.10 of the U.S. Food and Drug Administration publication, Food Code: 1999 Recommendations of the U.S. Public Health Service, Food and Drug Administration (1999), as modified and incorporated by reference in R9-8-107.
- 29. "Home health aide services" means assistance with bathing, dressing, grooming, eating, ambulating, or toileting.
- 30. "Homemaker services" means assistance with food preparation, cleaning, laundry, and housekeeping provided to a patient or a patient's family.
- 31. "Hospice" has the same meaning as in A.R.S. § 36-401.
- 32. "Hospice inpatient facility" means a health care institution licensed under this Article that provides hospice services to a patient requiring inpatient services.
- 33. "Hospice service" means an action identified in R9-10-808 that hospice staff provide for a hospice patient.
- 34. "Incident" means an unexpected occurrence that harms or has the potential to harm a patient during the provision of a hospice service.
- 35. "Informed consent" means documented authorization by a patient or a patient's representative for the provision of hospice services to the patient after a hospice staff member informs the patient or the patient's representative of the following:
 - a. A description of the hospice services;
 - b. A description of the expected benefits of the hospice services;
 - c. Alternatives to the hospice services;
 - d. Associated risks of the hospice services, including potential side effects and complications; and
 - The patient's right to withdraw authorization for the hospice services at any time.
- 36. "Inpatient beds" or "resident beds" has the same meaning as in A.R.S. § 36-401.

- 37. "Inpatient services" means sleeping accommodations and assistance, such as personal care and food preparation, provided to a patient at one of the following health care institutions:
 - a. A hospice inpatient facility licensed under A.R.S. Title 36, Chapter 4 and this Article; or
 - b. A hospital or nursing care institution licensed under A.R.S. Title 36, Chapter 4 and 9 A.A.C. 10.
- 38. "In-service education" means organized instruction or information related to hospice services provided to hospice staff under the direction of a licensed hospice.
- 39. "Interdisciplinary group" means a team composed of a physician, registered nurse, counselor, and social worker.
- 40. "Medical history" means the part of a patient's clinical record consisting of an account of the patient's health, including past and present illnesses or diseases.
- 41. "Medical records" has the same meaning as in A.R.S. § 12-2291.
- 42. "Neglect" means a pattern of conduct, without informed consent as defined in A.R.S. § 46-451(A), resulting in deprivation of food, water, medication, medical services, shelter, cooling, heating, or other services necessary to maintain minimum physical or mental health.
- 43. "Nonprescription drug" has the same meaning as in A.R.S. § 32-1901.
 44. "Nurse" means an individual licensed to practice practical or professional nursing under A.R.S. Title 32, Chapter 15.
- 45. "Nursing services" means hospice services provided according to R9-10-808(A)(2).
- 46. "Order" means a documented instruction given by a physician to provide a hospice service to a patient.
- 47. "Orientation" means initial instruction, information, and palliative care training provided to a new hospice staff mem-
- 48. "Palliative" means care of a terminally ill patient that is not curative and is designed for pain control or symptom management.
- 8-49. "Patient" means a terminally ill person individual who is receiving hospice services from a hospice.
- 50. "Pharmacist" or "licentiate in pharmacy" has the same meaning as in A.R.S. § 32-1901.
- 51. "Physician" means an individual licensed under A.R.S. Title 32, Chapter 13 or 17.
 52. "Prescription drug" has the same meaning as "prescription" in A.R.S. § 32-1901.
- 53. "Provider pharmacist" means a pharmacist who supplies medication to a long-term care facility and maintains patient profiles.
- 54. "Qualified" means meeting the requirements specified in a hospice's written job description for a staff position.
- 55. "Refuse" has the same meaning as in R18-13-302.
- 56. "Registered nurse" means an individual licensed under A.R.S. Title 32, Chapter 15.
- 57. "Representative" means a legal guardian, an individual acting on behalf of another individual under written authorization from the individual, or a surrogate as defined in A.R.S. § 36-3201.
- 9.58. "Research" means the use of a human subjects subject in the systematic study, observation, or evaluation of factors related to the prevention, assessment, treatment, and understanding of an illness.
- 59. "Residence" means a place where a patient is living or regularly staying, other than a health care institution at which a patient is receiving inpatient services.
- 60. "Respite" has the same meaning as "respite care services" in A.R.S. § 36-401.
- 61. "Service area" means the geographical boundary surrounding a hospice's administrative office in which the hospice provides hospice services, including inpatient services.
- 62. "Social worker" means an individual with a baccalaureate degree in social work in a program accredited or approved by the Council on Social Work Education.
- 40.63. "Staff" or "staff member" means employees and volunteers of a hospice an employee of a hospice, a volunteer for a hospice, or an agency or individual under contract with a hospice to provide a hospice service.
- 64. "Supervise" or "supervised" has the same meaning as "supervision" in A.R.S. § 36-401.
- 41.65."Terminally ill" means a medical diagnosis by a physician that a person an individual has a specific, progressive, normally irreversible disease which that will cause the person's individual's death in the foreseeable future six months or less.
- 66. "Therapeutic diet manual" means a written guidebook that designates the kind and amount of food intended to treat or ease a specific human disease or medical disorder.
- 12.67. "Volunteer" means a person who provides services to a hospice without compensation.

R9-10-802. **Hospice** General requirements Requirements

- A. No agency or organization shall establish, conduct or maintain a hospice without first obtaining a license from the Depart-
- B. Application for licensure as a hospice shall be made on forms provided by the Department.
- C. The hospice service plan shall be submitted with the licensure application and shall contain:
 - 1. The name of the governing authority and the person responsible for administering the hospice,
 - 2. The estimated average monthly patient census,
 - 3. The proposed geographic area to be served by the hospice,

- 4. A listing of services provided by the staff of the hospice and those services provided through contractual agreement,
- 5. The names and qualifications of persons or entities under contract to provide hospice services,
- 6. The names and qualifications of the hospice care team,
- 7. A description of how the hospice will utilize volunteers,
- 8. A description of the hospice's recordkeeping system, and
- 9. The current annual operating or proposed budget.
- **D.** The license shall not be transferable to a new location or a new owner and shall be the property of the Department. The license shall be returned to the Department immediately upon suspension or revocation of the license or upon termination of the hospice by the licensee.
- A hospice shall submit a new application for a change of ownership. A new application shall also be submitted when there is a change of location of the inpatient facility which is specified on the license. A hospice shall not be operated at the new location or under new ownership prior to the issuance of a new license for such location or owner. Hospice services which are to be provided at locations other than at the inpatient facility specified on the license shall give 30-days notice prior to a change in location of the agency or organization.
- F. The licensee shall notify the Department, in writing, at least 30 days prior to any change in:
 - 1. Contracts with providers of hospice services,
 - 2. Geographic service area, or
 - 3. Hospice services.
- G. The Department shall be notified at least 14 days prior to a change of Administrator.
- H. A license shall be valid for a period of 1 year. The hospice shall submit an application for renewal on a form provided by the Department which is delivered to the Department in a manner which documents receipt by the Department at least 90 days prior to expiration of the existing license.
- A. A person shall not operate a hospice without a hospice license from the Department.
- **B.** A licensed hospice shall comply with:
 - 1. The requirements in 9 A.A.C. 10, Article 1 and Article 8; and
 - 2. Federal and state laws, rules, and local ordinances related to the operation of a hospice.
- C. A licensed hospice shall:
 - 1. Have a governing authority,
 - 2. Provide hospice services required in R9-10-808, and
 - 3. Operate only in the hospice's service area.
- **D.** A licensed hospice engaged in medical research shall develop, implement, follow, review, and update written policies and procedures for:
 - 1. Securing the informed consent of a patient or patient's representative, before involving the patient in medical or experimental research;
 - 2. Conducting medical or experimental research;
 - 3. Ensuring that the patient's participation in medical or experimental research remains confidential; and
 - 4. Disclosing research data.
- E. A licensed hospice shall establish in writing and enforce a patient rights policy that includes the right to:
 - 1. Be treated with dignity, respect, and consideration;
 - 2. Receive individualized treatment according to a patient plan of care;
 - 3. Be free from:
 - a. Abuse;
 - b. Neglect;
 - c. Exploitation;
 - d. Retaliation for submitting a complaint against a hospice; and
 - e. <u>Discrimination based on race, national origin, religion, gender, sexual orientation, age, disability, marital status, diagnosis, or source of payment;</u>
 - 4. Be afforded privacy in correspondence, communication, visitation, financial affairs, hygiene, and receipt of hospice services;
 - 5. Be photographed only with authorization from the patient or the patient's representative; and
 - 6. File a complaint against a hospice.
- **F.** A licensed hospice shall conspicuously post in the reception area of the hospice's administrative office:
 - 1. The current Department-issued license;
 - 2. The current telephone number of the Department; and
 - 3. The location at which the following are available for review:
 - a. A copy of the most recent Department inspection report;
 - b. A list of hospice services;
 - c. A written copy of rates and charges, as required in A.R.S. § 36-436.03; and
 - d. The written patient rights policy required in subsection (E).

R9-10-803. Application for an Initial Hospice License; Application for Renewal of a Hospice License

- A. In addition to complying with the initial license application requirements in 9 A.A.C. 10, Article 1, an applicant for an initial hospice license shall submit to the Department an application form provided by the Department that includes:
 - 1. The hours of operation for the hospice's business or administrative office;
 - 2. A description of the hospice's service area;
 - 3. For each hospice service required in R9-10-808, other than inpatient services, whether a hospice employee, a hospice volunteer, or an agency or individual under contract with the hospice provides the hospice service;
 - <u>4.</u> For each health care institution providing inpatient services:
 - a. The name, address, and telephone number of the health care institution;
 - b. Whether the health care institution is:
 - i. A hospice inpatient facility operated by the applicant and licensed under this Article, or
 - ii. A hospital or nursing care institution licensed under 9 A.A.C. 10;
 - c. A copy of the health care institution's current Department license; and
 - d. The number of hospice inpatient beds; and
 - 5. Acknowledgement that a copy of each contract for provision of a hospice service, including inpatient services, is available for review by the Department.
- **B.** In addition to complying with the license renewal application requirements in 9 A.A.C. 10, Article 1, an applicant for renewal of a hospice license shall submit to the Department a renewal application form that includes:
 - 1. The information required in R9-10-803(A)(1) through R9-10-803(A)(5);
 - 2. The applicant's current hospice license number; and
 - 3. For the 12 months before the date on the renewal application, the total number of patients served.

R9-10-804. Medical advisor

- A. Each hospice shall have a medical advisor who is a physician and who shall have overall responsibility for the medical component of the hospice.
- **B.** The duties of the medical advisor shall be to:
 - 1. Serve as a consultant to the hospice care team;
 - 2. Assist in the development and review of patient and family care policies and procedures; and
 - 3. Serve as a resource to the patient's attending physician.

R9-10-803. R9-10-804. Hospice Administration

- A. Each hospice shall be organized and administered under 1 governing authority. The governing authority shall be ultimately responsible for the agency, establishing its policies and overseeing its operation.
- **B.** An advisory board shall be appointed. The members of the advisory board shall:
 - 1. Reside in the geographic service area defined in the hospice service plan;
 - 2. Have no direct or indirect financial interest in the hospice;
 - 3. Assist in adopting, annually reviewing and revising, as necessary, the written philosophy, policies and procedures for operation and administration of the hospice; and
 - 4. Meet at least annually.
- C. The governing authority shall appoint an administrator who shall either be:
 - 1. A physician;
 - 2. A registered nurse with a baccalaureate degree in nursing and at least 1 year of administrative or supervisory experience in community health programs; or
 - 3. A person with a baccalaureate degree in human services or administration and at least 1 year of administrative or supervisory experience in community health programs, or a person with 5 years of administrative supervisory experience with at least 1 year experience in community health programs.
- **D.** The administrator shall:
 - 1. Be responsible for the daily administration, supervision, maintenance and operation of the hospice;
 - 2. Designate, in writing, a qualified person, to act as administrator for those periods when the administrator is absent. If the administrator is absent for more than 30 continuous days, the designee shall have the qualifications prescribed by these rules for an administrator.
- A. A licensed hospice's governing authority shall:
 - 1. Appoint in writing a chief administrative officer, who may be the same individual as the governing authority, and who is either:
 - a. A physician;
 - b. A registered nurse with at least one year of experience in health care administration;
 - c. An individual with a baccalaureate degree in human services or administration and at least one year of health care administration experience; or

- d. An individual with five years of administrative experience, including at least two years of experience in health care administration;
- 2. Appoint in writing, or require that the chief administrative officer appoint in writing:
 - a. A medical director who is a physician, and who may be the same individual as the chief administrative officer; and
 - b. At least one nursing supervisor who is a registered nurse, and who may be the same individual as the chief administrative officer;
- 3. Approve, implement, and annually review all policies and procedures governing the hospice; and
- 4. Approve, or require that the chief administrative officer approve, each contract with an agency or individual to provide a hospice service.
- **B.** A licensed hospice's chief administrative officer shall:
 - 1. Supervise the day-to-day operation of the hospice;
 - 2. Designate, in writing, a staff member who meets one of the requirements in subsection (A)(1) to act as the chief administrative officer when the chief administrative officer is absent for more than seven continuous days;
 - 3. Designate a hospice staff member to supervise volunteers.
- C. A licensed hospice's medical director shall:
 - 1. Provide medical services to a patient:
 - a. If the patient does not have an attending physician; or
 - b. Whenever, in the medical director's judgment, the patient's attending physician does not meet the patient's medical needs;
 - 2. Serve as a consultant to each interdisciplinary group; and
 - 3. Serve as the physician member of each interdisciplinary group that would otherwise not have a physician member.
- **D.** A licensed hospice's nursing supervisor shall:
 - 1. Determine the number of nurses required to provide the nursing services identified in each patient's plan of care,
 - 2. Review and adjust nursing work schedules to ensure that nursing services identified in each patient's plan of care are provided to patients, and
 - 3. Ensure that the registered nurse on each interdisciplinary group coordinates the implementation of the plan of care for each patient assigned to that interdisciplinary group.

R9-10-805. Policies and procedures Hospice Staff

- A. Each hospice shall have written policies and procedures governing the following:
 - 1. Personnel policies;
 - a. The policies and procedures governing personnel matters shall require:
 - i. Verification that personnel are free from current pulmonary tuberculosis. Documentation shall include 1 of the following:
 - (1) Report of a negative Mantoux skin test within a year prior to date of employment or acceptance as a volunteer.
 - (2) Physician's report of a negative chest x ray,
 - (3) Report of an annual skin test indicating continuance of negative status, or
 - (4) A physician's statement provided each year noting that there is no symptomatic evidence of current pulmonary tuberculosis disease.
 - ii. Orientation, training, and continuing education requirements;
 - iii. Job descriptions and provisions for annual review and revision; and
 - iv. Confidentiality of personnel records.
 - b. Personnel records shall be maintained for all staff and shall contain:
 - i. A copy of a staff member's license or certificate, as applicable;
 - ii. Completed application form; and
 - iii. Job description.
 - 2. Volunteer services;
 - a. The policies and procedures for volunteers shall contain:
 - i. The philosophy, objectives and scope of the volunteer program;
 - ii. Qualifications for volunteers;
 - iii. The duties of the volunteers; and
 - iv. A written plan to orient volunteers to their duties.
 - b. Volunteer personnel records shall be maintained and shall contain:
 - i. Documentation of completion of a training program, certified by the Arizona Hospice Organization, for volunteers who provide direct patient care;
 - ii. Completed volunteer application form;
 - iii. Duties of the volunteer; and

- iv. Record of assignments and work hours.
- 3. Patient rights; Each hospice shall establish a written policy regarding the rights and responsibilities of patients and develop procedures for the implementation of such policies. Each patient and family shall:
 - a. Be treated with consideration, respect and full recognition of his dignity and individuality;
 - b. Receive individualized treatment;
 - e. Be provided adequate and humane services;
 - d. Be assured personal privacy, including right not to be photographed without written consent;
 - e. Be assured confidential handling of personal and medical records;
 - f. Be informed of charges for services provided by the hospice program; and
 - g. Have the right to refuse to participate in experimental research;
- 4. Admissions;
- 5. Hospice services offered; and
- 6. Inpatient services.
- B. A hospice which conducts research shall have written policies and procedures which shall provide for:
 - 1. Written, informed consent of each participant:
 - Protocols for conducting the research;
 - 3. Establishment of an interdisciplinary committee to review and approve research;
 - 4. Confidentiality of participant's identity; and
 - 5. Methods for disclosure of research data.
- C. The policies and procedures shall be:
 - 1. Annually reviewed and, if necessary, revised; and
 - 2. Available to staff, patients, families and the public.

A. A licensed hospice shall:

- 1. Form at least one interdisciplinary group;
- 2. Ensure that each patient receives the services designated in the patient's plan of care;
- 3. Have staff to meet the hospice needs of a patient and the patient's family 24 hours a day, seven days a week;
- 4. Have at least one registered nurse physically present 24 hours a day, seven days a week at a health care institution where a patient receives inpatient services;
- 5. Have a written job description for each staff position that identifies duties, skills, and qualification and education requirements;
- 6. Provide a staff orientation program;
- 7. Provide each staff member a minimum of two clock hours of annual in-service education in palliative care;
- 8. Have a written statement identifying the philosophy, objectives, and scope of the hospice's volunteer services; and
- 9. Maintain personnel records for each staff member containing:
 - <u>a.</u> A copy of a staff member's license or certificate, if applicable;
 - b. A completed application form or contract for the provision of services;
 - c. A job description;
 - d. A record of all orientation, in-service education, and continuing education; and
 - e. Evidence of compliance with subsection B(2).

B. A hospice staff member shall:

- 1. Complete orientation and in-service education required in subsections (A)(6) and (A)(7);
- 2. Before initially providing hospice services and every 12 months thereafter, submit one of the following as evidence of being free from infectious pulmonary tuberculosis:
 - a. A report of a negative Mantoux skin test administered within the last six months; or
 - b. If the staff member has had a positive Mantoux skin test for tuberculosis, a physician's written statement dated within the last six months, verifying that the staff member is free from infectious pulmonary tuberculosis.

R9-10-806. Patient Admissions

- A. Admission to a hospice shall be limited to individuals who have been diagnosed by their attending physician as terminally ill.
- **B.** Upon admission, each patient shall be oriented to the hospice's philosophy, policies, procedures, services, and patient rights. Each patient shall be provided a written copy of the patient rights. A written copy of the philosophy, policies, procedures, and services shall be provided upon request.
- **C.** Each patient admitted to a hospice shall have an attending physician.
- D. An assessment of the patient's medical, social, and psychological needs shall be made upon admission.
- A. Before admitting an individual as a patient, a hospice's chief administrative officer or designee shall require that the hospice obtain:
 - 1. The name of the individual's attending physician;
 - 2. Documentation that the individual is terminally ill, provided by:

- a. The individual's attending physician, and
- b. The hospice medical director or a physician member of a hospice interdisciplinary group; and
- 3. <u>Documentation from the individual or the individual's representative acknowledging that:</u>
 - a. Hospice care is palliative rather than curative;
 - b. The individual or individual's representative has received:
 - i. A list of hospice services, and
 - ii. The written patient rights policy required in R9-10-802(E); and
 - c. The individual or individual's representative may request a written copy of rates and charges, as required in A.R.S. § 36-436.03.
- **B.** At the time of patient admission, a hospice physician or a registered nurse shall:
 - 1. Assess a patient's medical, social, nutritional, and psychological needs; and
 - 2. Obtain informed consent from the patient or patient's representative.

R9-10-807. Patient eare plan Plan of Care

- A. A written care plan based upon the assessment of the patient's needs shall be prepared by the hospice care team upon admission of each patient. The patient and family shall be involved in preparing the care plan.
- B. Each care plan shall be reviewed by the hospice care team at least monthly.
- C. The plan of care shall contain:
 - 1. A complete assessment of the patient's care needs,
 - 2. Identification of appropriate living arrangements, and
 - 3. Types and frequency of prescribed therapy to be administered
- A. For each patient, the medical director, the patient's interdisciplinary group, and the patient's attending physician shall:
 - 1. Establish a documented plan of care based upon an assessment of the patient's medical, social, nutritional, and psychological needs;
 - 2. Attempt to involve the patient and the patient's family in the preparation of the plan of care;
 - 3. Review the plan of care as often as necessary, but at least monthly; and
 - 4. Revise the plan of care as necessary to meet the patient's care needs.
- **B.** The plan of care shall contain:
 - 1. A complete assessment of the patient's care needs, and
 - 2. Types and frequencies of planned hospice services.

R9-10-808. Hospice services Services

- A. Hospice services shall include nursing services, respite services, volunteer and bereavement services. Each hospice shall:
 - 1. Provide services either directly or by written contractual agreements with other providers or through the use of community resources;
 - 2. Maintain administrative control and responsibility for the provision of all services;
 - 3. Be responsible for ensuring that all services are provided in accordance with the patient's plan;
 - 4. Be available on call to patients and/or families services 24 hours a day, 7 days a week; and
 - 5. Have a registered nurse on staff who shall serve as coordinator of the hospice care team. The registered nurse shall be responsible for assessment of the patient, follow up visits with the patient, development and implementation of the therapeutic plan as prescribed by the physician and supervision of nursing care provided to the patient.
- **B.** Hospice services may include social services, counseling services, dietary services, homemaker services, home health aide services, habilitation services and inpatient services.
- **A.** A licensed hospice shall provide a hospice service:
 - 1. Through an employee of a hospice, a volunteer for a hospice, or an agency or individual under contract with a hospice to provide a hospice service;
 - 2. Specified in a patient's plan of care; and
 - 3. Twenty-four hours a day, seven days a week as necessary to meet the needs of a patient and the patient's family.
- **B.** A licensed hospice shall provide the following hospice services:
 - 1. Physician services that are within the scope of practice of a physician, provided by a physician;
 - 2. Nursing services that are within the scope of practice of a nurse, provided by:
 - a. A registered nurse; or
 - b. An individual:
 - i. Licensed under A.R.S. Title 32, Chapter 15 and 4 A.A.C. 19; and
 - ii. Operating under the direction of a registered nurse;
 - 3. Pharmaceutical services, including the administration of drugs or biologicals, provided according to R9-10-809;
 - 4. Dietary counseling services, including menu planning and the designation of the kind and amount of food appropriate for a patient, provided by a registered dietitian approved to work as a dietitian by the American Dietetic Association's Commission on Dietetic Registration;

- <u>5.</u> Home health aide services provided:
 - a. Through a home health agency licensed under 9 A.A.C. 10, Article 1 and Article 11; or
 - b. By a certified nursing assistant licensed under A.R.S. Title 32, Chapter 15;
- 6. Homemaker services, provided by a qualified individual;
- 7. Occupational therapy services provided by an occupational therapist licensed under and operating within the scope of practice authorized by A.R.S. Title 32, Chapter 34 and 4 A.A.C. 43;
- 8. Physical therapy services provided by a physical therapist licensed under and operating within the scope of practice authorized by A.R.S. Title 32, Chapter 19 and 4 A.A.C. 24;
- 9. Social services, including advocacy, referral, problem-solving, and intervention functions related to personal, family, business, and financial issues, provided by a social worker who with a baccalaureate degree in social work in a program accredited by the Council on Social Work Education;
- 10. Speech and language pathology services provided by a speech and language pathologist licensed under and operating within the scope of practice authorized by A.R.S. Title 36, Chapter 17 and 9 A.A.C. 16;
- 11. Spiritual counseling services, consistent with a patient's customs, religious preferences, cultural background, and ethnicity, provided by a qualified individual;
- 12. Volunteer services, supervised by a designated hospice staff member;
- 13. Counseling services other than spiritual and dietary counseling, provided by a qualified individual; and
- 14. <u>Inpatient services as defined in R9-10-801 provided to a patient for respite purposes, pain control, or symptom management.</u>
- C. A licensed hospice shall ensure that the following services are provided to a patient's family:
 - 1. Hospice respite services at a patient's residence or through inpatient services;
 - 2. Bereavement counseling, including social and emotional support, provided by a qualified individual for at least one year after the death of a patient; and
 - 3. Counseling determined by the interdisciplinary group to be:
 - a. Necessary while a patient is receiving services from the hospice, and
 - b. Related to a patient's illness.

R9-10-809. Hospice Pharmaceutical Services

- **A.** Drugs or biologicals may be administered to a patient by:
 - 1. A physician;
 - 2. A registered nurse;
 - 3. A physician assistant licensed under A.R.S. Title 32, Chapter 25 and acting within the physician assistant's scope of practice;
 - 4. A practical nurse licensed under A.R.S. Title 32, Chapter 15 and acting within the practical nurse's scope of practice.
 - 5. The patient, if pre-approved by the patient's attending physician; or
 - 6. Any other individual in accordance with applicable state and local laws, if the patient's plan of care specifies:
 - a. That the individual may administer a drug or biological, and
 - b. Which drug or biological the individual may administer.
- **B.** For each dose of drug or biological a hospice staff member administers to a patient, the hospice staff member shall document in the patient's clinical record:
 - 1. The date and time of administration;
 - 2. The name, strength, dosage, amount, and method of administration;
 - 3. The ordering physician's name;
 - 4. The signature of the individual administering the drug or biological;
 - 5. Any contraindications, such as symptoms or circumstances that render the use of a drug or biological for a patient inadvisable because of risk; and
 - 6. Any adverse reaction of the patient.
- **C.** A registered nurse shall:
 - 1. Report to the interdisciplinary group physician and the attending physician a patient's adverse reaction to a drug or biological or an error in administering a patient's drug or biological no later than 24 hours after identifying the adverse reaction or the error, and
 - 2. Submit an incident report to the hospice's medical director no later than 24 hours after identifying the adverse reaction or the error.
- **<u>D.</u>** A licensed hospice shall ensure that a health care institution providing inpatient services:
 - 1. Has a documented agreement with a pharmacist or provider pharmacist to assist in ordering of, storing of, administering of, disposing of, and recordkeeping for drugs or biologicals according to A.R.S. Title 32, Chapter 18, Title 36, Chapter 27, and 4 A.A.C. 23, Article 7;
 - 2. Stores nonprescription drugs or biologicals in the original manufacturer's package;

- 3. Stores a patient's prescription drugs or biologicals in the original prescription containers, labeled for the patient, in a separate storage space reserved for the patient;
- 4. Writes on a package or container in which a drug or biological is stored the date the package or container is first opened;
- 5. Stores drugs or biologicals according to the manufacturer's recommended temperatures;
- 6. Stores drugs or biologicals in a locked:
 - a. Room,
 - b. Cabinet,
 - c. Refrigerator, or
 - d. Box that is securely fastened within a refrigerator; and
- 7. Stores drugs or biologicals for external use, and eye, ear, and rectal medications separate from other drugs and biologicals.
- E. A licensed hospice shall dispose of discarded drugs according to 18 A.A.C. 13, Article 4.

R9-10-810. Hospice Dietary Counseling and Nutrition Services Required For a Patient Receiving Inpatient Services

- A. A licensed hospice shall ensure that a registered dietitian or a staff member under the direction of a registered dietitian plans menus for a patient that:
 - 1. Meet the nutritional needs of the patient based upon the patient's age, health needs, and patient plan of care;
 - 2. Are developed with consideration for the patient's:
 - a. Food preferences,
 - b. Customs,
 - c. Religious background,
 - d. Cultural background, and
 - e. Ethnic background;
 - 3. Are conspicuously posted at the health care institution providing inpatient services at least 24 hours before the meal is served; and
 - 4. Are maintained at the health care institution providing inpatient services for at least 30 days after the meal is served.
- B. A licensed hospice shall ensure that, unless otherwise required by a patient's plan of care and specified in a patient's menu, the patient is provided 48 to 64 ounces of water, three meals, and one snack a day, with not more than a 14-hour time span between the evening meal and the morning meal, including:
 - 1. Three servings of at least one-half cup of vegetables or 6 ounces of vegetable juice;
 - 2. Two servings of at least one-half cup of fruit or 6 ounces of fruit juice;
 - 3. Six servings of whole grain or enriched grain products, such as cereal, bread, rice, or pasta, with a serving consisting of one slice of bread or one-half to one cup of cereal or other grain product;
 - 4. Two servings of milk, yogurt, cottage cheese, or cheese, with a serving consisting of one cup of milk or yogurt, one and one-half ounces of cheese, or six ounces of cottage cheese; and
 - 5. Two servings of protein, neither of which can be the same as a serving in subsection (B)(4), such as meat, fish, poultry, cheese, egg, peanut butter, peas, dry beans, or lentils, with a serving consisting of two to three ounces of lean meat without bone, one cup dry beans or legumes, four tablespoons of peanut butter or other nut butter, or two eggs.

R9-10-811. Hospice Infection Control, Environmental Safety, and Sanitation

- <u>A.</u> A licensed hospice shall develop and implement communicable disease and infection control policies and procedures including:
 - 1. Using standard and contact precautions that comply with 9 A.A.C. 6, Article 3;
 - 2. Reporting communicable diseases according to 9 A.A.C. 6, Article 2;
 - 3. For patients receiving inpatient services, isolating from other patients a patient who has a communicable disease;
 - 4. Transporting and processing soiled linens and clothing;
 - 5. Sterilizing equipment and supplies;
 - 6. Maintaining and storing sterile equipment and supplies; and
 - 7. Ensuring that a staff member is free from communicable diseases when providing a hospice service.
- **B.** A licensed hospice shall dispose of biohazardous medical waste according to 18 A.A.C. 13, Article 14.
- **C.** A licensed hospice shall ensure that a reusable item:
 - 1. Is sterilized before the item is assigned to a patient for use,
 - 2. <u>Is assigned to only one patient for continuous personal use, and</u>
 - 3. Is cleaned after each use.
- **D.** A staff member providing hospice services shall wash the staff member's hands and exposed arms with soap and water:
 - a. <u>Immediately before and after providing hospice services to a patient,</u>
 - b. After using the toilet, and

- c. As often as necessary to remove soil and contamination;
- <u>E.</u> A licensed hospice shall ensure that food is free from spoilage, filth, or other contamination, and is safe for human consumption when served to a patient by a staff member.
- **F.** A staff member handling food shall:
 - 1. Clean the staff member's hands and forearms as required in § 2-301 of the U.S. Food and Drug Administration publication, Food Code: 1999 Recommendations of the U.S. Public Health Service, Food and Drug Administration (1999), as modified and incorporated by reference in R9-8-107; and
 - 2. Keep the staff member's hair from contacting food or food-contact surfaces.

R9-10-812. Variances

- A hospice may submit to the Department a written request for a variance from any rule in this Article, accompanied by documentation justifying the proposed alternative means of meeting the requirements which shall not adversely affect the health and safety of its patients.
- **B.** An approved variance shall be for a period not to exceed 1 year and may be renewed upon reapplication with documented justification. Reapplication shall be made at least 60 days prior to the expiration of the current variance.

R9-10-809. R9-10-812. Clinical record Hospice Recordkeeping; Patient Clinical Record

- A. A clinical record shall be established and maintained for each patient receiving hospice services.
- B. The clinical record shall contain:
 - 1. Identification data.
 - 2. Consent and authorization forms.
 - 3. Pertinent medical history,
 - 4. Physician orders,
 - 5. Initial and subsequent assessments,
 - 6. Plan of care, and
 - 7. Documentation of all services provided.
- C. Records shall be safeguarded against loss, destruction and unauthorized use. A licensed hospice shall:
 - 1. Develop, implement, follow, and annually review and update documented policies and procedures for recordkeeping, including electronic recordkeeping, if applicable;
 - 2. Maintain confidentiality of patient records, as required in A.R.S. Title 12, Chapter 13, Article 7;
 - 3. Establish and maintain a clinical record for each patient containing:
 - a. The patient's name and age;
 - b. Drug or biological allergies or sensitivities;
 - c. <u>Informed consent forms and authorization forms</u>;
 - d. Medical history;
 - e. Physician orders, signed and dated by the physician;
 - f. Documentation of an assessment required in R9-10-806(B)(1) and R9-10-807(B)(1);
 - g. Plan of care; and
 - h. Documentation of all hospice services provided to the patient; and
 - 4. Maintain for Department review and inspection documentation or verification required by this Article.

R9-10-810. R9-10-813. Hospice Quality assurance Assurance

- A. Each hospice shall establish a written quality assurance plan.
- B. The quality assurance plan shall provide for an ongoing assessment of the quality and appropriateness of care provided.
- C. The hospice shall use the findings to correct identified problems and to revise hospice policies, if necessary.
- **D.** Documentation shall be maintained showing evidence that the findings and means of correcting problems were reviewed by the governing authority.

A licensed hospice shall have a documented quality assurance plan that identifies procedures for:

- 1. Collecting data on the hospice services provided:
- <u>2.</u> <u>Interpreting the data collected to determine the:</u>
 - a. Adequacy of the hospice services provided,
 - b. Efficiency of the systems used by the hospice to deliver hospice services, and
 - c. Effectiveness of hospice staff in meeting the needs of a patient and the patient's family;
- 3. Identifying, documenting, and evaluating an incident; and
- 4. As a result of the data collected or the incidents identified:
 - a. Making changes or taking corrective action:
 - b. Reporting findings, changes made, and corrective actions taken to the governing authority; and
 - c. Evaluating the effectiveness of the changes made.

R9-10-811. R9-10-814. Impatient service requirements Hospice Inpatient Facility General Requirements

A. General

- 1. A hospice providing inpatient services shall comply with all applicable federal, state and local laws, rules, and codes pertaining to physical plant, health, and safety.
- 2. Twenty-four hour nursing services, which are sufficient to meet total nursing needs and which are in accordance with the patient care plan, shall be provided. Each patient shall receive treatments, medications and diet as prescribed and shall be kept comfortable, clean, well-groomed and protected from accident, injury and infection.
- 3. There shall be at least 1 registered nurse on each tour of duty to supervise direct patient care.
- 4. The visitation policy shall provide for visiting hours which are flexible and shall include visitation by infants, children, and pets.

B. Pharmaceutical services

- 1. Administration of medications
 - a. Self-administration of medications by patients is not permitted unless ordered by the patient's physician or performed in a predischarge training program under the supervision of a licensed nurse.
 - b. Adverse drug reactions shall be reported by a licensed nurse immediately to the attending physician and an entry shall be made in the patient's medical record.
 - e. Medication errors shall be reported to the attending physician and an incident report prepared.
 - d. Medications shall be administered only by a licensed nurse or physician.
 - e. Drugs and/or biologicals shall be administered as soon as possible after the dose is prepared by the same licensed nurse who prepared the dose for administration, except that a physician may administer a drug that has been prepared at his direction by a licensed nurse.
- 2. Storage and disposition of medications
 - a. Except for unit dosages, each patient's medications shall be stored in original prescription containers in a separate storage space reserved for each patient.
 - b. A record shall be maintained which lists on a separate sheet for each type of controlled drug the date and quantity received, signature of nurse accepting delivery, date and time of administration, name of patient, dose, physician's name, signature of person administering the dose, and the balance of drug remaining.
 - e. All medications shall be kept under secure conditions such as in a locked drug room or cabinet.
 - d. Medications requiring refrigeration shall be kept in a separate locked box which is securely fastened within the refrigerator, unless the refrigerator is locked or is located in a locked drug room. Temperature of the refrigerator shall not exceed 45°F.
 - e. Medications for external use, and eye, ear, and rectal medications shall be kept separate from other medications.
 - f. Medications which have exceeded their expiration dates, those which are unusable or which are not to be released to the patient upon discharge and those which have an illegible or missing label shall be separated from other medications and disposed of by a pharmacist. If medications are destroyed by a pharmacist who is not an employee of the Arizona State Board of Pharmacy, the administrator or his designee shall witness the destruction.

C. Nutrition services

- 1. A registered dietitian or a food service supervisor under the direction of a registered dietitian shall:
 - a. Assess the nutritional status and needs of the patients; and
 - b. Assist in the development, implementation and evaluation of the patient care plan.
- 2. Planning of menus and food supplies
 - a. Menus shall be planned to meet the nutritional needs of patients in accordance with physician's orders.
 - b. The meals for each day shall contain:
 - i. Four servings of fruits and vegetables;
 - ii. Four servings of whole grain or enriched cereals and breads;
 - iii. Two servings of milk or dairy products; and
 - iv. Two servings of protein: meat, fish, poultry, cheese, egg, peanut butter, peas, beans, lentils, or equivalent.
 - e. At least 1 serving of at least 1 of the following 4 food components shall be offered at the first snack of the day, and at least 1 serving each of at least 2 of the following 4 food components shall be offered for the bedtime snack:
 - i. Fruit and/or vegetable or full-strength fruit or vegetable juice;
 - ii. Whole grain or enriched cereal or bread;
 - iii. Milk or other dairy product; and
 - iv. Meat, fish, poultry, cheese, egg, or peanut butter.
 - When a therapeutic diet is prescribed for the patient, snacks provided shall comply with the diet prescription.
 - e. Menus and snacks shall be planned at least 1 week in advance.
- Food shall be prepared by methods that conserve nutritive value, flavor, and appearance and shall correspond with the items on the menu.

D. Sanitation and infection control

- 1. The facility shall be kept clean, safe and free from hazards, offensive odors, accumulations of dirt, miscellaneous debris, dust, lint, discarded equipment, and materials.
- 2. Written procedures shall be established to prevent the transmission of infection. The procedures shall provide for:
 - a. Investigation, control and prevention of infections in the facility;
 - b. Aseptic and isolation techniques to be followed by all personnel; and
 - e. Daily environmental cleaning procedures, including type of cleaning material and equipment, to be used.
- 3. Contaminated dressings and other similar materials shall be disposed of in a sanitary landfill approved by the Department of Environmental Quality. Where such an approved sanitary landfill is not available, contaminated wastes shall be disposed of by incineration facilities approved by the county air quality control agency. In those counties which have no county air quality control agency, the incineration facilities shall meet the standards of the Arizona Department of Environmental Quality.
- 4. Bedpans, urinals, emesis basins, wash basins, and other personal nursing items shall be thoroughly cleaned after each use and sanitized. All such equipment shall not be used if chipped or otherwise damaged.
- 5. All catheters, irrigation sets, drainage tubes or other supplies or equipment for internal use which cannot be autoclaved or otherwise sterilized shall be used only once and discarded.
- 6. Each lavatory in the facility shall have a soap dispenser and a dispenser with disposable paper towels or a hand drying device.
- 7. Tubs, portable commodes, showers and shower chairs shall be thoroughly cleaned after each patient's use.
- 8. Linens shall be handled, stored, processed and transported in such a manner as to prevent the spread of infection.
- 9. Staff shall wash their hands immediately after providing personal or nursing care to each patient.

E. Physical requirements

- 1. The inpatient facility shall be maintained in good repair.
- 2. The temperature in the patient care areas shall be maintained between 70 82° F.
- 3. Patient care areas shall be designated and equipped for the comfort and privacy of each patient and family members.
- 4. The inpatient facility shall have:
 - a. Designated space for private patient and family visits;
 - b. Accommodations for family members to remain with the patient throughout the night;
 - e. Accommodations for family privacy after a patient's death;
 - d. Decor which is homelike in design and function; and
 - e. Patient rooms which shall:
 - i. Be equipped with, or conveniently located near, toilet and bathing facilities;
 - ii. Be at or above ground level;
 - iii. Contain a bed, bedside table, bedside chair, and reading light for each patient;
 - iv. Have closet space that provides security and privacy for clothing and personal belongings;
 - v. Be clean and well ventilated;
 - vi. Contain no more than 4 beds;
 - vii. Measure at least 100 square feet for a single patient room or 80 square feet for each patient for a multipatient room; and
 - viii. Be equipped with an audio-visual system for calling the staff member on duty.

F. Disaster preparedness

- 1. There shall be a current written plan of operation with procedures to be followed in the event of fire, explosion or other disaster or threat to patient safety. The plan shall:
 - a. Contain procedures for prompt transportation of patients and records, instructions regarding the location and use of alarm systems and fire-fighting equipment, information regarding methods of containing fires, procedures for notification of the appropriate persons and agencies and specifications, routes, and procedures for evacuation.
 - b. Designate the specific place to which patients may be evacuated, and the detailed arrangements to provide adequate shelter, beds, food and water, and nursing care, including medications and other services critical to the well-being of patients who must be moved.
- 2. Employees shall be oriented to disaster preparedness within the first week of employment. If an employee has not received such orientation, the employee shall not be permitted to be the only employee in the facility until such orientation is completed. The disaster program shall include ongoing training and a drill for disaster other than fire, at least semiannually, for personnel so that each employee can promptly and correctly perform specific duties in case of disaster.
- 3. There shall be at least 1 fire drill per shift during each calendar quarter.
- A person shall not operate a hospice inpatient facility without a hospice license and a hospice inpatient facility license from the Department.

- **B.** A licensed hospice inpatient facility shall:
 - 1. Have one governing authority that is the same as the governing authority of the hospice;
 - 2. Provide hospices services only to a patient admitted according to R9-10-806 to the hospice;
 - 3. Conspicuously post in the reception area of the hospice inpatient facility:
 - <u>a.</u> The current Department-issued license;
 - b. The current telephone number of the Department; and
 - <u>c.</u> The location at which the following are available for review:
 - i. A copy of the most recent Department inspection report;
 - ii. A list of hospice services;
 - iii. A written copy of rates and charges, as required in A.R.S. § 36-436.03; and
 - iv. The written patient rights policy required in R9-10-802(E); and
 - 4. Comply with all applicable requirements in R9-10-802, R9-10-804, R9-10-805, R9-10-807, R9-10-808, R9-10-809, R9-10-810, R9-10-811, R9-10-812, and R9-10-813.
- C. A licensed hospice inpatient facility shall:
 - 1. Establish and implement a visitation policy that allows individuals of all ages to visit a patient 24 hours a day, and
 - 2. Allow a visitor to bring a domesticated animal to visit a patient.

R9-10-815. Application for an Initial Hospice Inpatient Facility License; Application for Renewal of a Hospice Inpatient Facility License

- A. In addition to complying with the initial license application requirements in 9 A.A.C. 10, Article 1, an applicant for an initial hospice inpatient facility license shall submit to the Department the applicant's current hospice license number.
- **B.** In addition to complying with the license renewal application requirements in 9 A.A.C. 10, Article 1, an applicant for renewal of a hospice inpatient facility license shall submit to the Department:
 - 1. The applicant's current hospice inpatient facility license number,
 - 2. The applicant's current hospice license number, and
 - 3. The number of inpatient beds.

R9-10-816. Hospice Inpatient Facility Physical Plant Standards

- **A.** A licensed hospice inpatient facility shall comply with:
 - 1. All applicable local, state, and federal physical plant codes and standards; and
 - 2. <u>Life Safety Code requirements in R9-1-412(A)(4).</u>
- B. A licensed hospice inpatient facility shall ensure that the hospice inpatient facility has a design and decor that:
 - 1. De-emphasizes the institutional character of the hospice inpatient facility.
 - 2. Has characteristics that are comparable to those found in domestic settings, and
 - 3. Allows the patient to use and display personal belongings.
- **C.** A licensed hospice inpatient facility shall provide a patient a sleeping area that:
 - 1. <u>Is shared by no more than four patients;</u>
 - 2. Measures at least 80 square feet per patient;
 - 3. Has walls from floor to ceiling and at least one doorway;
 - 4. Is at or above ground level;
 - 5. Is vented to the outside of the hospice inpatient facility;
 - 6. Has a working thermometer for measuring the temperature in the sleeping area;
 - 7. For each patient, has a:
 - a. Bed,
 - b. Bedside table,
 - c. Bedside chair,
 - d. Reading light,
 - e. Privacy screen or curtain, and
 - f. Closet or drawer space;
 - 8. Is equipped with a bell, intercom, or other mechanical means for a patient to alert a staff member;
 - 9. Has at least one doorway no more than 20 feet from a room containing a toilet and a sink;
 - 10. Is not used as a passageway to another sleeping area, to a toilet room, or to a bathing room;
 - 11. Contains one of the following to provide sunlight:
 - a. A window to the outside of the hospice inpatient facility, or
 - b. A transparent or translucent door to the outside of the hospice inpatient facility; and
 - 12. Has coverings for windows and for transparent or translucent doors that provide patient privacy.

- **D.** A licensed hospice inpatient facility shall provide:
 - 1. For every six patients, a toilet room that contains:
 - a. At least one working toilet that flushes;
 - b. At least one sink with running water;
 - c. Grab bars;
 - d. A mirror;
 - e. Space for staff to assist a patient;
 - f. A bell, intercom, or other mechanical means for a patient to alert a staff member; and
 - g. An operable window to the outside of the hospice inpatient facility or other form of ventilation;
 - 2. For every 12 patients, at least one working bathtub or shower accessible to a wheeled shower chair, with a slip resistant surface, located in a toilet room or in a separate bathing room;
 - 3. For a patient occupying a sleeping area with one or more other patients, a separate room in which the patient can meet privately with family members;
 - 4. Space in a lockable closet, drawer, or cabinet for a patient to store the patient's private or valuable items;
 - 5. A room other than a sleeping area that can be used for social activities:
 - 6. Sleeping accommodations for family members;
 - 7. For staff and visitors, a designated toilet room other than a patient toilet room that contains:
 - a. At least one working toilet that flushes, and
 - b. At least one sink with running water;
 - 8. If the hospice inpatient facility has a kitchen with a cooking unit, a cooking unit vented to the outside of the hospice inpatient facility; and
 - 9. Space separate from sleeping areas, toilet rooms, bathing rooms, and drug storage areas designated for administrative responsibilities.

R9-10-817. Hospice Inpatient Facility Food Service

- **A.** A licensed hospice inpatient facility shall:
 - 1. Prepare and serve meals to a patient as specified in the patient's menu required in R9-10-810(A), or
 - 2. Contract with a food establishment licensed under 9 A.A.C. 8, Article 1 to prepare and serve meals to a patient as specified in the patient's menu required in R9-10-810(A).
- **B.** If a licensed hospice inpatient facility with more than 20 patients prepares and serves food to a patient, the hospice inpatient facility shall:
 - 1. Be licensed under 9 A.A.C. 8, Article 1; and
 - 2. Maintain at the hospice inpatient facility a copy of the hospice inpatient facility's food establishment license.
- C. If a licensed hospice inpatient facility with 20 or fewer patients prepares and serves food to a patient, the hospice inpatient facility shall:
 - 1. Have a therapeutic diet manual with a copyright date not more than five years old available for use by a staff member who prepares food;
 - 2. Maintain at least a one-day supply of perishable food and at least a three-day supply of non-perishable food;
 - 3. If canned food is served, serve only commercially canned food:
 - 4. Rinse raw fruits and raw vegetables with water before cooking or serving;
 - 5. Maintain a thermometer accurate to $\pm 3^{\circ}$ F in each refrigerator;
 - 6. Maintain foods requiring refrigeration at 41° F or below,
 - 7. Maintain frozen foods as required in §§ 3-402.11, 3-501.11, and 3-501.12 of the U.S. Food and Drug Administration publication, Food Code: 1999 Recommendations of the U.S. Public Health Service, Food and Drug Administration (1999), as modified and incorporated by reference in R9-8-107;
 - 8. Cook food as required in §§ 3-401.11, 3-401.12, and 3-401.13 and reheat food as required in § 3-403.11 of the U.S. Food and Drug Administration publication, Food Code: 1999 Recommendations of the U.S. Public Health Service, Food and Drug Administration (1999), as modified and incorporated by reference in R9-8-107;
 - 9. Thaw food as required in § 3-501.13, cool food as required in §§ 3-501.14 and 501.15, and maintain hot and cold holding temperatures as required in § 3-501.16 of the U.S. Food and Drug Administration publication, Food Code: 1999 Recommendations of the U.S. Public Health Service, Food and Drug Administration (1999), as modified and incorporated by reference in R9-8-107;
 - 10. Follow the requirements for highly susceptible populations in § 3-801 of the U.S. Food and Drug Administration publication, Food Code: 1999 Recommendations of the U.S. Public Health Service, Food and Drug Administration (1999), as modified and incorporated by reference in R9-8-107;
 - 11. Store food that has been opened or removed from its original container in a dated covered container, a minimum of six inches off the floor, and protected from contamination; and
 - 12. Keep tableware and eating utensils clean and in good repair.

- **D.** If a licensed hospice inpatient facility contracts for the preparation and delivery of food to the hospice inpatient facility, the hospice inpatient facility shall:
 - 1. Maintain at the hospice inpatient facility a copy of the food establishment's license; and
 - 2. Maintain at the hospice inpatient facility equipment necessary to store, refrigerate, and reheat food to meet the dietary needs of a patient.

Hospice Inpatient Facility Environmental Safety and Sanitation R9-10-818.

A licensed hospice inpatient facility shall:

- 1. Store a toxic substance as defined in A.R.S. § 49-961 or a hazardous material as defined in A.R.S. § 36-301 in a labeled container in a locked area other than a food preparation or storage area, a dining area, a medication storage area, or a sleeping area;
- 2. Except for medical supplies needed for a patient, such as oxygen, store a flammable liquid as defined in A.R.S. § 28-601:
 - a. In the original labeled container or a safety container,
 - In a locked area inaccessible to a patient, and <u>b.</u>
 - Outside of the hospice inpatient facility;
- Provide water sufficient to meet the hygiene needs of each patient;
- Provide hot water at a temperature between 90° F and 120° F for patient use;
- Maintain the temperature of the hospice inpatient facility between 70°F and 82°F;
- Keep garbage and refuse in covered containers lined with plastic bags while inside the hospice inpatient facility;
- Remove from the inside of the hospice inpatient facility garbage and refuse at least once every 24 hours;
- Dispose of garbage and refuse according to 18 A.A.C. 13, Article 3;
- Keep the hospice inpatient facility free from:
 - a. A condition or situation that may cause a patient or an individual to suffer physical injury;
 - b. Accumulations of dirt, debris, dust, lint, or discarded equipment and materials; and
 - c. <u>Insects and rodents</u>;
- 10. Develop and implement policies and procedures specifying:
 - a. A cleaning schedule for at least the following:

 - i. Laundry,ii. Toilet rooms,
 - iii. Bathing rooms,
 - iv. Sleeping areas, and
 - v. Kitchens, and
 - b. Types of cleaning products and equipment to be used;
- 11. Store, launder, and transport linens away from food storage, kitchen, and dining areas; and
- 12. Provide and continuously stock a working soap dispenser and either a dispenser with disposable paper towels or a working hand-drying device in each toilet room located in the hospice inpatient facility.

R9-10-819. **Hospice Inpatient Facility Disaster Preparedness**

A licensed hospice inpatient facility shall:

- 1. Develop and maintain on the premises a written evacuation plan for staff to follow in the event of fire, explosion, or other disaster or threat to patient safety that includes:
 - a. Assigned personnel responsibilities;
 - b. Procedures for transportation of patients and, if possible, records:
 - c. Location of and instructions for use of alarm systems;
 - d. Location of and instructions for use of fire-fighting equipment, including methods of containing fires;
 - e. Procedures for notification of local, state, or federal agencies appropriate to respond to the disaster:
 - An evacuation map;
 - Procedures for arranging adequate shelter, beds, food, water, and essential nursing care, including drugs and biologicals, at an alternative location; and
 - The location and list of emergency supplies on the premises:
- 2. Conspicuously post written evacuation maps at the hospice inpatient facility;
- 3. Require that staff review an evacuation plan and conduct an evacuation drill, without patient participation, at least once every six months during each shift;
- 4. Maintain for 24 months at the hospice inpatient facility records of each evacuation drill including:
 - <u>a.</u> The date and time of the evacuation drill;
 - b. The names of staff participating in the evacuation drill;
 - A critique of the drill; and
 - d. Recommendations for improvement, if applicable;

- 5. Train all staff on the evacuation plan during the first seven days of employment; and
- 6. Require one staff member who has received evacuation plan training to be present at the hospice inpatient facility at all times.

NOTICE OF PROPOSED RULEMAKING

TITLE 17. TRANSPORTATION

CHAPTER 5. DEPARTMENT OF TRANSPORTATION COMMERICAL PROGRAMS

PREAMBLE

1. Sections affected

R17-5-212

Rulemaking Action

Amend

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 28-366

Implementing statutes: A.R.S. §§ 28-332 and 28-5204

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 8 A.A.R. 1194, March 22, 2002

4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: George R. Pavia, Department Rules Supervisor

Address: Administrative Rules Unit

Department of Transportation, Mail Drop 507M

3737 N. 7th St., Suite 160 Phoenix, AZ 85014-5079

Telephone: (602) 712-8446 Fax: (602) 241-1624

E-mail: gpavia@dot.state.az.us

Please visit the ADOT web site to track progress of this rule and any other agency rulemaking matters at www.dot.state.az.us/about/rules/index.htm.

5. An explanation of the rule, including the agency's reasons for initiating the rule:

R17-5-212 defines the motor carrier hearing process and establishes emergency hearing requirements to ensure public safety. This rulemaking arose from proposed agency action in the five-year review report, F98-0401, approved by the Governor's Regulatory Review Council on May 5, 1998. At the time of the five-year rule review, this Section was numbered R17-4-440.

This rule revision will also update both statutory references and rule language to conform current standards for clarity, conciseness, and understandability of the Governor's Regulatory Review Council and the Secretary of State.

6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

None

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

Enforcement of federal and state motor carrier regulations focus on the identification and resolution of safety violations, which can reduce deaths, personal injuries, and their related costs. The motor carrier safety hearing process provides an opportunity for motor carrier owners and drivers cited for safety violations to respond to a citation or to resolve a safety issue prior to a hearing. The motor carrier safety hearing process also provided emergency hearings for motor carriers with significant safety violations that may result in a cost avoidance to both enforcement and the general driving public by removing motor carrier transports identified as being unsafe. The motor transport owners and drivers will experience costs for repairing equipment to meet federal and state statutes and rules. They may also experience attorney fees in defending against a citation. Motor carriers may experience a loss of income when equipment is impounded, being repaired, or while enforcement personnel examine the cited motor carrier vehicle to ensure the cited safety issues have been resolved.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Questions concerning the economic impact statement may be directed to the official listed in item #4.

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

No oral proceeding is scheduled for this rulemaking. Written, faxed, e-mail comments or a request for an oral proceeding may be made to the agency official listed in item #4, Monday through Friday, 8:00 a.m. until 4:30 p.m. If no oral proceeding is requested the public record in this rulemaking will close at 4:30 p.m. on July 5, 2002.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 17. TRANSPORTATION

CHAPTER 5. DEPARTMENT OF TRANSPORTATION COMMERICAL PROGRAMS

ARTICLE 2. MOTOR CARRIERS

Section

R17-5-212. Motor Carrier Safety: Hearing Procedures Procedure

ARTICLE 2. MOTOR CARRIERS

R17-5-212. Motor Carrier Safety: Hearing Procedures Procedure

- A. Scope. This rule applies exclusively to enforcement actions conducted pursuant to R17 4 435 through R17 4 435.05 and R17-4-436 and A.R.S. Title 28, Chapter 19.
- B. Complaint.
 - 1. Every action to enforce the provisions of R17-4-435 through R17-4-435.05 and R17-4-436 and A.R.S. Title 28, Chapter 19, except for enforcement actions pursuant to subsection (G) of this rule, shall be commenced by the filing of a complaint signed by the Director. A copy of the complaint shall be served on all parties in accordance with subsection (D) of this rule.
 - 2. The complaint shall contain:
 - a. A designation of the state of Arizona through the Motor Vehicle Division as the petitioner.
 - b. A designation of the party or parties from whom relief is requested as the respondent.
 - e. The facts upon which the alleged violations are based.
 - d. The statutes, rules, or regulations alleged to be violated.
 - e. The relief requested.
 - f. A statement that the respondent was served with written notice that a violation was not remedied by the date specified in the violation notice.
 - g. A statement that failure to file an answer within 15 days of service of the complaint shall constitute a default and be treated as an admission of the allegations contained in the complaint and a waiver of the respondent's right to contest the relief prayed for.

- h. The name, address, and telephone number of the attorney representing the petitioner.
- 3. The original of the complaint shall be filed with the Hearing Office.

C. Order to Show Cause.

- 1. Upon the filing of the complaint, the Hearing Office shall forthwith issue its order for the respondent to appear and show cause at an administrative hearing why the relief requested in the complaint should not be granted.
- 2. The date for the Order to Show Cause hearing shall be not less than 20 days or more than 60 days from the filing date of the complaint
- 3. Service. All service required by this rule shall be by certified mail or personal delivery. Service by mail is complete upon mailing. Personal service on a partnership or corporation shall be made in accordance with Rule 4.1 of the Arizona Rules of Civil Procedure. Personal service may be made by an employee of the Motor Vehicle Division or the Department of Public Safety. Proof of service shall be filed with the Hearing Office.

E. Answer.

- 1. Within 15 days of service of the complaint, the respondent shall file an answer with the Hearing Office and serve a copy on petitioner's attorney.
- 2. The answer shall admit or deny each allegation of the complaint and shall state any defenses raised. Allegations which are not denied shall be deemed admitted for all purposes at the hearing.

F. Default.

- 1. A respondent who fails to file an answer within 15 days of service of the complaint shall be in default.
- 2. A respondent who is in default is deemed to have admitted all the allegations contained in the complaint.
- 3. Upon default, the Hearing Office may enter an order granting the relief requested in the complaint.

G. Danger to the Public Safety.

- 1. Notwithstanding any other rule to the contrary, where the Director has determined that a danger to the public safety exists, a copy of the order signed by the Director in accordance with R17-4-439(F) as well as the report of violations shall be served upon the respondent as soon as practical. An emergency hearing shall be held within 10 days of the issuance of the Director's order. A response shall be filed by the respondent at least 2 days prior to the emergency hearing.
- 2. At the emergency order to show cause hearing, the hearing officer shall determine if sufficient cause exists for continuing the registration or license suspension pending a hearing on the merits pursuant to these rules. Failure to find sufficient cause for an emergency suspension shall not prevent the continuation of a normal enforcement action pursuant to this rule, in which case the usual provisions for enforcement actions under this rule shall apply.

H. Settlement.

- 1. At any time prior to the issuance by the Hearing Office of a final decision, the parties may agree to disposition of the action through settlement. All settlements shall be approved by the Director and the respondent and submitted to the Hearing Office. The Hearing Officer shall incorporate the settlement in a final decision.
- 2. The settlement of any action constitutes a waiver by both parties of any rights to an appeal or other review under he Administrative Review Act, A.R.S. § 12 901 et seq. and A.A.C. R17 4 912.
- **L** Unless otherwise specifically prescribed in this rule, the general rules for hearing and appeal procedures set forth in A.A.C. Title 17, Chapter 4, Article 9 apply.

A. Scope.

- 1. This Section applies only to motor carrier enforcement action under:
 - a. R17-5-202 through R17-5-207;
 - b. R17-5-209; and
 - c. A.R.S. Title 28, Chapter 14.
- 2. <u>In a manufacturer, motor carrier, shipper, or driver enforcement hearing under this Section, the Department shall follow administrative law procedure prescribed under A.A.C. Title 17, Chapter 1, Article 5, except for unique motor carrier safety hearing procedure prescribed under subsection (B) through (I).</u>

B. Initiation of Proceedings, Pleadings.

- 1. The Division Director shall initiate a hearing under this Section by:
 - a. Signing a complaint that cites a motor carrier for an alleged infraction prescribed under subsection (G); and
 - b. Serving the cited motor carrier with a hearing notice within 15 days after the complaint signing date as prescribed under subsection (D).
- 2. After the Division Director signs a complaint, the Executive Hearing Office shall act on the Division Director's behalf through completion of administrative proceeding prescribed under this Section.

C. Order to Show Cause.

- 1. When a complaint is filed, the Executive Hearing Office shall immediately issue a summons for a respondent to appear at an administrative hearing to explain why the Division should not grant the requested relief.
- 2. The Executive Hearing Office shall hold a hearing under this Section within 60 days after the complaint's filing date.

- **D.** Service. The Executive Hearing Office shall:
 - 1. Send notice of a complaint and order to show cause by certified mail as prescribed under A.R.S. § 28-5232(B); and
 - 2. Maintain a proof-of-service file that establishes the mailing date as the date of service.

E. Answer.

- 1. Within 15 days after service of a complaint notice, a respondent shall answer the complaint by:
 - a. Filing a written response with the Executive Hearing Office; and
 - <u>b.</u> <u>Serving the Division's attorney with a copy of the response.</u>
- 2. A respondent's written answer shall contain:
 - a. An admission or denial of each complaint allegation; and
 - b. A list of any defense that the respondent intends to raise during a hearing.
- 3. In a hearing, the Executive Hearing Office shall consider any allegation not denied in the answer as an admission to the allegation.

F. Default.

- 1. The Executive Hearing Office shall find a respondent failing to file an answer within 15 days after a complaint's service date prescribed under subsection (D)(2) in default.
- 2. If the Executive Hearing Office finds a respondent in default, the Executive Hearing Office shall:
 - a. Consider the respondent's default as an admission of any complaint allegation; and
 - b. Enter an order granting the relief requested in the Division's complaint.
- 3. A respondent may cure a default by following Arizona Rules of Civil Procedure, Rule 66.
- <u>G.</u> Emergency Motor Carrier Hearings; Scope.
 - 1. The Division Director shall initiate an emergency motor carrier hearing process according to provisions prescribed under R17-5-211(F) by:
 - a. Issuing a complaint according to the hearing scope as prescribed under A.R.S. § 28-5232(C); and
 - b. Ordering immediate suspension of the motor carrier's license, registration, or both, as prescribed under A.R.S. § 28-5232(A).
 - 2. The Executive Hearing Office shall set an emergency hearing date within 30 days after the date of the complaint notice.
 - 3. The Division shall issue a complaint notice and order to show cause compliant to A.A.C. Title 17, Chapter 1, Article 5, with the following contents:
 - a. The Division designated as the petitioner on the state's behalf;
 - b. The respondent's name and the basis of fact, including a listing of any alleged violation of Department statute, rule, or regulation;
 - c. The relief sought by the Division; and
 - d. An original copy of the written violation notice served upon the respondent.
 - 4. The parties may resolve a complaint for the Division Director's emergency order before the hearing date.
 - a. A settling party shall file any settlement condition with the Executive Hearing Office.
 - b. <u>Upon complaint settlement, both petitioner and respondent terminate the right to receive additional administrative review.</u>
 - 5. At an emergency motor carrier safety hearing, an Executive Hearing Office administrative law judge shall determine if the respondent:
 - a. Was operating on the public highway and that such operation created a danger to the public safety; and
 - b. Was responsible for the danger, and whether the hearing will prevent or remedy a further danger to the public safety.
 - 6. Upon a finding of responsibility, the administrative law judge shall order that the motor carrier's registration and operator's driver license suspension continue.
 - 7. If a respondent fails to appear at an emergency motor carrier safety hearing, any suspension previously ordered remains in effect until the respondent appears and meets all requirements as prescribed under A.R.S. § 28-5232(F).
- **H.** Upon a finding of responsibility, the Division Director shall follow penalty provisions prescribed under A.R.S. §§ 28-5232(F) and 28-5238.
- **L.** A respondent may request judicial review of a motor carrier safety hearing proceeding that follows procedure prescribed under A.R.S. § 28-5239.